EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL 2327
U.S. DISTRICT JUDGE JOSEPH R. GOODWIN

Deposition of ALAN GARELY, M.D., relating to the following cases in Wave 1 of MDL 200:

Carey Beth Cole, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00483

Amanda Deleon, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00358

Rose Gomez, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00344

Donna Zoltowski, et al. V. Ethicon, Inc.
Civil Action No. 2:12-cv-00811

DEPOSITION OF ALAN GARELY, M.D., FACOG, FACS

Friday, April 15, 2016

New York, New York

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Deposition of ALAN GARELY, M.D., FACOG, FACS pursuant to Notice, on the the 15th day of April 2016, at Loews Regency Hotel, 540 Park Avenue & 61st Street New York, New York, commencing at 9:00 a.m.; before DANA N. SREBRENICK, a Certified Court Reporter, a Registered Realtime Reporter and Notary Public within and for the State of New York.

with almost all of them.

Q We'll come back to the products in a little bit. Am I correct, Dr. Garely, that you are not an expert in biomaterials?

A Well, I'm familiar with biomaterials, but I'm not a biomaterial engineer.

Q Okay. You're not a polymer scientist, correct?

A That is correct.

Q You're not a trained pathologist, correct?

A That is correct.

Q And you're not board certified in pathology, correct?

A That is correct.

Q You're not trained in neuropathology; is that correct?

A That is correct.

Q And you're not an epidemiologist, correct?

A That is correct.

Q Have you ever been involved in drafting instructions for use for a medical device?

A When -- I've been involved in advising

companies in formulating the instructions for use, but I've actually not physically put the pencil to the paper and written up those instructions myself.

Q Tell me what you have done in advising companies on instructions for use.

A Well, when I was asked to be an expert by Ethicon, back in the late '90s, to come on-board and evaluate the TVT sling, I was sent as part of a group to Sweden and we learned the procedure from the inventors of the TVT procedure.

When we came back to the United States, we were intimately involved in formulating the IFUs to help instruct and educate physicians in the United States on how to use the product.

Q So that was the TVT Retropubic, the original TVT sling?

A Yes, ma'am.

Q As best as you can remember, what was your involvement with respect to the TVT IFU at the time, did you receive a draft of it and review it and provide commentary, what did you do exactly with respect to the IFU?

A It was almost 20 years ago. I just recall that we would have a lot of meetings with the people who were putting the product out. We -- we did everything from educational preparation, educational materials, to helping design the way that the product looked.

We went through different iterations of the needles and the mesh, and we discussed things that belonged in the IFU so that physicians could be properly educated on the use of the product.

Q As you sit here today, can you recall actually reviewing draft versions of the IFU and providing feedback on those draft versions?

A There were so many papers that we were looking at and formulating that to say that I specifically remember any one of those, I can't get my mind around that, no.

Q Dr. Garely, is it fair to say that you do not hold yourself out as an expert in product labeling?

A I don't understand the question.

Q You don't consider yourself an expert in formulating labels for medical devices and

what components those labels need to have?

A I guess I'm not familiar with what a label would be.

Q Fair point. Am I correct that you don't hold yourself out as an expert of what the requirements of the contents of an instructions for use should be?

A Well, I do believe that I'm an expert when it comes to the instructions for use when it applies to products that I'm familiar with, yes.

Q Have you reviewed regulatory guidances or regulations that address what the requirements of device labeling are?

A Only in documents that I reviewed from internal documents of when companies were writing their IFUs and they had background information to go on, but that would have been the only time that I would have reviewed those documents.

Q And what are the documents that you reviewed?

A Whatever -- from this case or from the Bard case, when I had the internal documents

from the companies where they were trying to come up with IFUs and they were talking about the regulatory issues regarding the IFUs, those were the documents that I saw.

Q Have you ever reviewed FDA regulations relating to labeling and what needs to go into product instructions for use?

A I don't know that I've specifically seen that document.

Q Have you ever reviewed the document that is known as the FDA Blue Book Memo on what needs to go into instructions for use?

A That one sounds familiar. I just don't recall having -- what I would have read in it. But it does sound familiar.

Q It sounds familiar to you, but as you sit here today, you're not sure whether or not you've looked at that particular document?

A Correct.

Q Have you ever reviewed Ethicon's standard operating procedures regarding what information needs to go into instructions for use?

A I don't know if I've looked at that

manual, only what I've seen from the internal documents and discussion of what should be included and excluded from the IFU.

Q Okay. As you sit here right now, you can't recall looking at a particular Ethicon labeling standard operating procedure, SOP document, that lays out what needs to be in an instructions for use, correct?

A Based on the internal documents that I read, I don't even know if such a thing existed because they were choosing to exclude information that would have helped physicians to use the product better.

So if there was some guideline, some guideline that would have told them what to do, I don't know that they followed it. Apparently they just chose indiscriminately to include or exclude information that could have or could not have been helpful to physicians.

MS. KABBASH: Move to strike as nonresponsive.

BY MS. KABBASH:

Q My question, Doctor, is as you sit here today, am I correct that you do not recall

reviewing a particular Ethicon standard operating procedure document related to what should go in labeling?

A I don't recall.

Q Am I correct that you are not an expert in design control procedures and requirements for bringing a product through development?

A I don't know what you mean by "design control."

Q So there are various FDA regulations and requirements that govern a company's process of bringing a product through the design stages, and eventually to market, they're called design controls. And are you familiar with FDA regulations that govern what a company must accomplish in their design controls?

A Only from my participation in products coming from the drawing board to marketing. That's my only experience with that.

Q And you would not hold yourself out as an expert in FDA regulations on design controls, correct?

A That would be correct.

Q You would not be able to speak to how,

abdominal sacrocolpopexy in thousands of women, correct?

A That's correct.

Q And that's going back to your fellowship, correct, or even to your residency?

A Oh, no, I did not use these devices in residency.

Q Okay.

A Since fellowship, yes. But the majority clearly -- my fellowship was two years. The majority of these cases were not as a trainee, but as an attending physician.

Q So you clearly believe that polypropylene is an appropriate graft to use to treat prolapse in an abdominal approach, correct?

A Correct, in an abdominal approach.

Q Doctor, let me try in a sense to sort of cut to the chase on one particular issue. Is it your opinion that the polypropylene is fine to use to treat prolapse, but it should not be used in a transvaginal approach; is that -- if I had to kind of boil down your opinion, is that what your opinion is?

A That's my opinion.

Q Well, let me kind of get -- we'll get more into this later, but you have various opinions in your report, Doctor, about alternative designs that don't use mesh arms, don't use trocars, and you propose some alternative materials at one point in your report.

At the end of the day, isn't it correct that your opinion is regardless of mesh arms, regardless of the use of trocars, regardless of pore size, you don't think that mesh should be implanted vaginally to treat prolapse; is that correct?

A In its current state, I believe that that's correct.

Q And when you say "in its current state," what are you referring to?

A I'm referring to the fact that in medicine, we have research and development and new products come along all the time, and I'm optimistic and hopeful that we will develop a product that can be implanted vaginally, but that device does not exist in its current form

doing with Boston Scientific?

A And the IVS Tunneller.

Q So you did use the IVS Tunneller to treat an anterior defect?

A Not anterior, you said apical.

Q I apologize, I misspoke. Have you ever used transvaginal mesh to treat an anterior defect?

A When I used the Prolene mesh on the device with Boston Scientific, we were also using it to treat anterior defects.

Q Am I correct that you have never implanted Gynemesh PS transvaginally in any women?

A I think you're correct.

Q You've never implanted the Prolift, correct?

A I've never implanted the Prolift.

Q And you've never implanted the Prolift+M, correct?

A Correct.

Q You've never implanted Bard's Avaulta?

A Correct.

Q You've never implanted AMS's Elevate?

A That's correct.
Q Have you ever looked at a piece of Gynemesh PS under the microscope?
A No.
Q Have you ever looked at a piece of Prolift+M under the microscope?
A Well, I'd like to just add to that in that I've not physically put the mesh under the microscope, but I have papers that I have reviewed that have pictures of the material under the microscope, so I've looked at photographs of microscopic material, but I've never actually physically taken the mesh and put it under the microscope myself.
Q You've not performed benchtop testing on Prolift or Gynemesh PS mesh or tools, correct?
A Correct.
Q And you've not performed benchtop testing on Prolift+M mesh or tools, correct?
A Correct.
Q You have not performed animal studies on Prolift or Gynemesh PS mesh, correct?
A Correct.

Q And you've not performed animal studies on Prolift+M mesh, correct?

A Correct.

Q Dr. Garely, do you agree that it is not a standard -- strike that. Let me start again.

Do you agree that it would not be a deviation from the standard of care for a doctor to have utilized Prolift and implanted Prolift into women?

A I'm sorry, could you repeat the question?

Q Sure. Would it have been a deviation from the standard of care for a doctor to implant Prolift in women, for a trained pelvic floor surgeon to implant Prolift in women?

A Given the information that was presented to a surgeon back in the initial time of release, I don't think it would have been against the standard of care. I think today if someone were to implant it, I think it would be against the standard of care.

Q I assume the same answer would apply to Prolift+M?

A Correct.

of patients that can get mesh erosion. Do I know that that's related to mesh contracture? No, I do not know that.

Q And is that opinion based on your personal experience in what you've seen in your practice?

A And review of the literature. I don't recall reading in the literature that there were mesh contracture that contributes to a clinical scenario.

Q Doctor, are you able to identify specific meshes that you have explanted?

A I am.

Q Let me ask you first about Prolift and Prolift+M. Have you -- let's start with Prolift. Have you explanted meshes that you have known to be Prolift or Gynemesh PS?

A Yes.

Q And how do you know that they are Prolift or Gynemesh PS?

A I base it on a few factors. One is where the patient had their surgery and who the surgeon was. Two is the patient telling me what the procedure was. Three would be looking at

the operative report. Four would be explanting the material and looking at it.

Q Are you able to tell by looking at Prolift that it's Prolift? Do you recognize it when you explant it?

A I usually do.

Q How do you recognize it?

A Because the blue lines in the white mesh.

Q Are you able to tell when you explant it whether it's Prolift or Prolift+M?

A I've tried to distinguish between the two. I don't know that -- given the way that the meshes are explanted, sometimes it's very difficult.

Q How many meshes have you explanted that you have known to be either Prolift or Prolift+M?

A Somewhere between 10 and 20 for sure. Over that, I don't know for sure.

Q Does your office have some method of tracking what mesh is explanted in any way other than what you described to me already? Do you document that in some way when you explant a

mesh and identify what type of mesh it is?

A I don't specifically document the brand name of the mesh, no.

Q For the -- and am I correct that for the 10 to 20 mesh explants that you're referring to, you would not be able to distinguish whether they are Prolift versus Prolift+M, correct?

A Only based on the patient's operative report or in discussion with their surgeon.

Q So if you did not find out about it through the patient's surgeon or the patient telling you what procedure they had, you would not be able to know by looking at it whether it was a Prolift or Prolift+M?

A I think it's hard for me.

Q For any of those explants, did you ever view any of them under the microscope?

A No.

Q Would it have been your practice to send those explants to pathology?

A A hundred percent.

Q Okay. Is it fair to say that you would not have performed a pathological analysis of those explants, correct?

A No, I don't do pathological analysis.
Q You're not trained for that, correct?
A I'm not trained for that. In addition, the pathologist usually just documents what it is I've explanted in terms of foreign material mesh and then they'll talk about inflammation and whatever else is -- attached to the mesh. It's not like I'm looking for them to give me a diagnosis of cancer or anything.
Q Are you able to tell from when you're doing the explant, whether the mesh was implanted via a vaginal route versus an abdominal route?
A Absolutely.
Q And in what way can you tell that?
A Because vaginal applied mesh is almost always just at the apex, and transvaginal mesh, applied mesh, is almost always on the anterior wall, apex or posterior wall. It has to do with the anatomic location of where the mesh is explanted.
The difference is also with Prolift and Prolift+M, because of the arms and contracture and shrinkage of the mesh, I can almost always

Q Have you ever reviewed Federal statutes or regulations on whether a product is misbranded or adulterated?

A I do not recall.

Q As you sit here today, is it fair to say that you don't have an understanding of what Federal statutes or regulations address misbranding or adulteration of products?

A Not today, no.

Q Am I correct that you will not be offering opinions at trial regarding whether Ethicon complied with FDA requirements or regulations in its sale of Prolift or in its labeling for Prolift?

A Just what I put in my expert report on 2A.

Q You indicate here that Ethicon brought Prolift to market without FDA 510(k) clearance, correct?

A That is correct.

Q Am I correct that --

MR. MATTHEWS: I can state in my place that he will not be offering an opinion on that at trial. You can ask him about it all you

want.

MS. KABBASH: On 2A?

MR. MATTHEWS: 2A.

MS. KABBASH: Okay. I will rely on that representation.

BY MS. KABBASH:

Q Dr. Garely, would you agree with me that there is no transvaginal mesh kit to treat prolapse that has been the subject of more studies than Prolift? Would you agree with that?

A I have not done an independent research into the other mesh kits for me to be able to say that Prolift has had the most amount of research. I cannot say that.

Q So as we sit here today, you don't know whether that's true or not?

A Not to my -- not to my memory.

Q Do you know if Prolift has more RCTs in particular studying it than other manufacturers' mesh kits?

A I have not delved into the research of the other mesh kits. I cannot say.

Q So you have not studied the quality and

recall that?

A Well, there were so many different iterations of the pore size based on whether it was at rest or whether it was at stretch or tension or whether -- the axis of the stretch occurred. So know that greater than 1 millimeter was good and 2.4, that was better than 1, but there was a distortion of the pores that occurred, once the tissue was implanted -- once the material was implanted into the tissue.

Q On what are you basing your opinion that there was a distortion of the pores that occurred? What body of information is that opinion based on?

A It's in my -- somewhere in my report, but it was based on internal documents from research that I had looked at that was done by Johnson & Johnson.

Q Okay. Are you pointing to any -- besides company documents, which you've just discussed, is there any medical literature that you can specifically point me to that concludes that the pores in Prolift mesh deform or distort?

A Yes.
Q Which study?
A Well, I cite different papers in my footnotes in different parts of this paper.
Q Where are you?
A I'm on page 12. And talking about excessive scarification and shrinkage, when there's shrinkage, there's a decrease in the pore size. That's reference 22.
Q Reference 22 is to Ethicon cadaver labs, correct?
A That reference for that point.
Q But my question is, can you point me to a study piece -- a published -- peer-reviewed published medical literature?
Let me ask a more precise question. Can you point me to any peer-reviewed published medical literature that has concluded that the pores in Ethicon's Prolift mesh collapse or deform to be less than 1 millimeter?
A Well, the -- there's the same mesh that was used on abdominal hernia repairs demonstrated shrinkage. I don't -- I'd have to see the papers right in front of me to recall

whether or not they said that the pore size actually shrunk. I need a minute to just take a look.

Q Why don't we go off the clock for a second, and you can take a look to find it.

A Okay.

(Whereupon, a brief recess is taken.)

THE WITNESS: Okay.

BY MS. KABBASH:

Q Okay?

A What I was relying on was the internal documents from Ethicon which are cited as number 6 and number 7. Those would be --

Q I apologize. What page are you on?

A It would be page 9. The top paragraph number 3 with reference number 6 and reference number 7. Those were internal documents done by Ethicon.

So off the top of my head, no, I cannot cite a published paper, but Ethicon knew from their own internal research that the pores did shrink down to less than 1 millimeter.

Q Okay. So just to make the record

clear, as we sit here right now, you cannot point me to a piece of published medical literature which concludes that the pore size of Prolift mesh deforms to less than 1 millimeter, correct, as we sit here right now?

A Well, there's -- I mean, I don't have my PubMed in front of me, but if I'm -- and I don't know that I can recall specifically that Klausterhoffen made a note about pore size. But I think that one of his papers did discuss shrinkage of pore size, but I can't be a hundred percent certain without looking at the paper.

Q And you have not cited that paper in your report, correct?

A I don't think I did.

Q Okay. You also have -- let's go to page 11 of your report, which I think we're already here. Opinion number 6, you say, "As the Prolift mesh scars in, the resulting shrinkage or contracture of the tissues surrounding the mesh can entrap nerves, deform the vagina and pelvic anatomy," et cetera. And then you go on to say below that, you discuss nerve entrapment with chronic pain. Do you see

that?

A I do.

Q You say sometimes after one year there are no complaints and then complaints happen -- oh, I'm sorry, you're quoting something here, an Ethicon surgeon panel meeting, and it goes on to say, "Often the result of tiny nerves in the granuloma and that's just a matter of" -- strike that.

In this opinion, you were making -- you were opining that patients may suffer complications from tiny nerves that get entrapped in the mesh, correct?

A I was opining that I agreed with Ethicon's surgeon panel's assessment. I was agreeing with them.

Q And that opinion is that tiny nerves can get entrapped in the mesh due to contraction, correct?

A Yes.

Q Okay. And you also hold this same opinion with respect to Prolift+M, correct?

A I do.

Q Okay. Would you agree that the

entrapment of tiny nerves, to the extent that it happens, is something that has to be viewed under a microscope? In other words, you cannot clinically discern the entrapment of tiny nerves in mesh, right? You have to view that under a microscope to see that, correct?

A Well, if a patient has pain at the site of where the mesh is, and if you take the mesh out and it relieves the pain, we're all I'm sure in agreement that nerves cause pain, so there would be nothing else other than nerve issues surrounding the mesh that would be causing the pain.

So do I need a microscope to confirm nerve presence in a mesh? I do not. But if you wanted to say, hey, are there nerves in this mesh, then you would need to do appropriate nerve stains and use a microscope, but from a clinical perspective, that's not something that you would care about the patient, if patients got better by removing the mesh.

Q From a clinical perspective, if you -- if a patient was in pain, and you removed the mesh, you would -- and the patient got better

and the pain got better, you would deduce or make an assumption that there were nerves in the mesh, correct?

A That's fair.

Q To actually investigate the explants and see if there is evidence of nerves in the mesh, you would have to take that mesh, put it on a slide, and put it under a microscope and look at it, correct?

A Well, it's a matter -- it's a point of semantics, but yes, if you wanted to actually prove it, it's not something that's done in common practice.

Q I think plaintiff's expert pathologist might disagree with that, but...

Am I correct that you were not trained in interpreting what can be viewed on explant slides under a microscope? In other words, not only have you not put a mesh slide under a microscope and looked at it, even if you had, you are not trained in how to interpret what you're seeing on that slide; is that correct?

A Just from what I know from basic histology and pathology in medical school. And

I did do two months of pathology as a resident as well.

Q And that was about 20 years ago?

A I did that probably -- I did that rotation in my second year of residency, that was 1990.

Q Is it fair to say that if you -- if we had a mesh that was on a slide and it got put under the microscope, you would need the assistance of a pathologist to be able to properly and reliably interpret what was on that mesh slide, correct? Or some other professional with a background other than yours?

A I could probably muddle through it on the bigger structures, but I would have a problem on the smaller things.

Q Tiny nerves in particular, correct?

A I'm not really good at looking at tiny nerves under the microscope.

Q You don't typically use a microscope to make treatment recommendations and decisions for your patients, correct?

A I do not.

Q And you don't use a microscope in order

to assess how to treat complications if you have patients with complications, correct?

A I do not.

Q Do you know which stains need to be used so that nerves can be seen on a mesh slide under a microscope?

A I know for a fact that I used to know the answer to this, but as I sit here today, I do not recall.

Q Okay. Do you know what level of magnification needs to be used so that nerves can be viewed in a mesh explant?

A Now I feel bad that I didn't pay more attention in pathology. I do not recall.

Q Okay. If we move to page 12 -- I'm coming to a good stopping point soon, I'm just trying to get there. I'm not trying to starve you or anything, believe me.

As we come to page 12 of your report, you have opinion number 7, and in the second paragraph of opinion 7 or paragraph 7, you say, "As the parts of the mesh arms of Prolift kits incorporate into tissue via a scarring process, they pull asymmetrically on the center mesh

Q Am I correct, Doctor, that in this opinion, regarding the asymmetrical pulling on the arms and the roping and curling opinion, that in your report as you articulate these opinions, you have not relied on peer-reviewed medical literature to support these opinions?

We've just discussed the cadaver lab that you just mentioned. We've discussed your experience with the 10 to 20 explants. Am I correct that in support of your roping and curling opinion and your asymmetrical pulling opinion, you are not relying in this report on peer-reviewed medical literature, correct?

A I don't -- I don't know what else to call it when the -- when the arms rope and curl, other than roping and curling.

MS. KABBASH: Move to strike.

BY MS. KABBASH:

Q You have not cited in your report on these two points any peer-reviewed medical literature that supports your opinions on roping, curling and asymmetrical pulling, correct?

A I don't know that it's not included in

any of the references that I've put forth into my expert report, but off the top of my head, I can't recall a specific paper where they noted roping and curling.

Q Okay. Why don't we break for lunch.

(Whereupon, a luncheon recess is taken.)

MR. MATTHEWS: He'll read and sign.

BY MS. KABBASH:

Q Dr. Garely, we took a break for lunch. Are you ready to proceed?

A Yes, ma'am.

Q Dr. Garely, will you be offering an opinion at trial to a reasonable degree of medical certainty that polypropylene mesh degrades after implantation in the body?

A Only what I've referenced in my expert report.

Q You've referenced in your expert report -- you have a paragraph on page 23 that there's a statement in the IFU, "The material in Gynemesh is not absorbed nor is it subject to degradation or weakening by the action of tissue enzymes is contradicted by Ethicon internal